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U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT
850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

Telephone: [718] 965-5300 [Ext 5053]

February 4, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Richard Solomon, President
R. H. Cosmetics, Corp.
80 39th Street
Brooklyn, New York 11232

Ref: 33-NYK-97
"Dermetics Australian Tea Tree Oil"
"Barth's Australian Tea Tree Oil"
"Daggett & Ramsdell Australian Tea Tree Oil Skin Tonic"

Dear Mr. Solomon:

This letter is in reference to the above listed products which are manufactured and repacked by your firm. The labeling indicates that the products contain tea tree oil, and that they are intended to be used in the treatment or prevention of various disease conditions to affect the structure (or function) of the body. These three products are subject to regulation under various OTC final rules. A drug product subject to a final rule that is initially marketed on or after the effective date must be in compliance with the final rule unless it is the subject of an approved new drug application (NDA).

The "Dermetics Australian Tea Tree Oil" is labeled to "Fight Nail fungus . . . To fight dandruff . . . Fights athlete's foot . . . For skin problems such as pimples, cuts, bruises, burns, and fungus." The "Barth's Australian Tea Tree Oil" is labeled as "Ideal for skin problems such

as pimples, cuts, bruises, burns, athlete's foot and fungus." Additionally, the "Daggett & Ramsdell Australian Tea Tree Oil Skin Tonic" product is labeled to "fight acne, purifies by killing bacteria." Based on their labeled indications, "Dermetics Australian Tea Tree Oil," "Barth's Australian Tea Tree Oil," and "Daggett & Ramsdell Australian Tree Oil Skin Tonic" are subject to the final rule for *Topical Antimicrobial Drug Products*, Title 21, Code of Federal Regulations, (CFR), Subpart C-Topical Antifungal Drug Products, Part 333.210; and Subpart D -Topical Acne Drug Products (21CFR 333.310), and/or the final rules for *Miscellaneous External Drug Products*, Subpart H - Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis, (21CFR 358.710).

The three products fail to meet the requirements of the final rules in that tea tree oil is not an acceptable ingredient for any of the indications listed. Therefore, these three products are "new drugs" as defined by the Federal Food, Drug and Cosmetic Act (the Act), Section 201(p) which may not be marketed in interstate commerce under Section 505(a) of the Act since they are not approved under Section 505(b). The products are also misbranded under Section 502(f)(1) because the labeling fails to bear adequate directions for use. The "Daggett & Ramsdell Australian Tea Tree Oil Skin Tonic" is further misbranded for failure to declare alcohol content as required under Section 502(e) of the Act.

In addition, all drug products are misbranded under Section 502(o) of the Act, because your establishment is not registered according to Section 510 of the Act, and the drug products are not listed as required by 21 CFR Part 207.20(a). Attached for your convenience is form FDA 2656 "Registration of Drug Establishment."

The above list of violations is not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure that all of your firm's products are in compliance with all requirements of the Act and its implementing regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Domestic Compliance Branch, Food and Drug Administration, 850 Third Avenue, Brooklyn, New York 11232, Attention: Anita Fenty, Compliance Officer.

Sincerely,

Charles W. Sedgwick
Acting District Director

cc: Mr. Dennis Schoen, President
Barth Vitamin Corp.
100 Banks Avenue
Rockville Center, New York 11571
(516)763-7612

attachments
Form FDA 2656 Registration of Drug Establishment
Form FDA 2657 Drug Product Listing
Form FDA 2658 Registered Establishment's Report of Private Label Distributors

O: addressee w/attachments
cc: HFR-NE1 through NE100
cc: HFR-NE100
cc: HFR-NE140(Q.A. File)
cc: HFR-NE140(AF)
cc: HFR-NE150(Woyshner/A. Williams)
cc: HFR-NE150(Comstat)
cc: HFA-224
cc: HFC-210(CFN: 2415851)
cc: EF(R. H. Cosmetics, Corp.)
cc: Warning Letter file (33-NYK-97)